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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,140	09/27/2000	Gary Kruh	FCCC 98-02	5331

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EXAMINER

CHEN, SHIN LIN

ART-UNIT	PAPER NUMBER
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1632

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DATE MAILED: 08/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/647,140

Applicant(s)

KRUH ET AL.

Examiner

Shin-Lin Chen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8-59 is/are pending in the application.
- 4a) Of the above claim(s) 8-44, 52-55 and 59 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-3, 5 and 45-51 is/are allowed.
- 6) ☒ Claim(s) 4, 6 and 56-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Applicants' amendment filed 6-16-03 has been entered. Claim 7 has been canceled.

Claims 4, 6, 45-51 and 56-58 have been amended. Claims 1-6 and 8-59 are pending and claims 1-6, 45-51 and 56-58 are under consideration.

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claim 6 is rejected under 35 U.S.C. 101 because it is directed to non-statutory subject matter. Applicants' amendment filed 6-16-03 necessitates this new ground of rejection. The claims encompass naturally occurring nucleic acid molecules, which are not considered patentable subject matter. See MPEP 2105. This rejection could be overcome by amending the claims to recite a "an isolated nucleic acid molecule".

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 4 recites the limitation "said MOAT-B transporter protein" in lines 5-6. There is insufficient antecedent basis for this limitation in the claim. Applicants' amendment filed 6-16-03 necessitates this new ground of rejection.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants' amendment filed 6-16-03 necessitates this new ground of rejection.

Claim 4 has been amended to read on an isolated nucleic acid comprising introns and exons and the exons comprise sequence which are identical to SEQ ID No. 1 and encodes MOAT-B transporter protein. The newly amended claim 4 is considered new matter because the amendment filed 6-16-03 fails to point out where in the specification the description of such a nucleic acid has been provided. The specification fails to provide support for a nucleic acid comprising introns and exons and the exons comprising sequence that are identical to SEQ ID No. 1 and encodes MOAT-B transporter protein.

4. Claims 56-58 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the

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invention and is repeated for the reasons set forth in the preceding Official action mailed 2-13-03 (Paper No. 16).

Applicants cite Zaman et al., 1994, and US 5,766,880 and argue that drug sensitivity assays and anticancer agent efflux assays For MRP are known in the art. Applicants further argue that MRP and MOAT were characterized as transporters capable of effluxing cytotoxic drugs and the high degree of homology implicates MOAT-B as a transporter (amendment, p. 15, 16). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 2-13-03 (Paper No. 16). The cited references Zaman and US 5,766,880 have not been provided in the amendment filed 6-16-03. Examiner has difficulty in responding to the particular section cited in those references. However, although there are some homology between various domains of MOAT-B and MRP as indicated in Table 1 of the present invention, the % identity between those domains range from 27.9% to 61.6%. As discussed in the preceding Official action mailed 2-13-03 (Paper No. 16), there is no evidence of record that MOAT-B protein can mediate cellular efflux of any anticancer agent in a host cell and inhibition of MOAT-B protein activity could restore anticancer drug sensitivity. It was known in the art protein function is unpredictable from mere amino acid sequence. The specification (page 57, lines 12-22) indicates that whether MOAT-B, C, D, E and cMOAT can confer cytotoxic drug resistance as MRP remain to be seen. Thus, whether MOAT-B would have same biological function as MRP remain unclear and the limited homology between MRP and MOAT-B can not predict the biological function of MOAT-B.

Applicants argue that one skilled artisan could link promoter used to express MOAT to a reporter gene to determine whether the test compound has effect on MOAT activity or on the

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promoter (amendment, p. 16). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 2-13-03 (Paper No. 16) and the reasons set forth above. The claimed method does not specify how to distinguish the effect of the test compound on MOAT-B activity or on the promoter activity that expresses said MOAT-B. Since whether MOAT-B protein can mediate cellular efflux of any anticancer agent in a host cell is still unclear and the lack of distinguishment between the effect of the test compound on MOAT-B activity and on the promoter activity in the claimed methods, one skilled in the art at the time of the invention would not know how to screen a test compound for inhibition of MOAT mediated transport. One skilled in the art would require undue experimentation to practice over the full scope of the invention claimed.

Conclusion

Claims 4, 6 and 56-58 are rejected. Claims 1-3, 5 and 45-51 are in condition for allowance.

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (703) 305-1678. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on (703) 305-4051. The fax phone number for this group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Shin-Lin Chen, Ph.D.

A handwritten signature in black ink, appearing to read 'Shin-Lin Chen', is positioned to the right of the typed name.